K091761

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

TELEFLEX ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8083
Fax: 919-433-4996

B. Contact Person

OCT 2 9 2009

William Heard
Regulatory Affairs Specialist

C. Date Prepared

May 15, 2009

D. Device Name

Trade Name: TELEFLEX ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port (ISIS Tube)
Common Name: Tracheal Tube

Classification Name: Tracheal Tube (W/Wo Connector) (21 CFR 868.5730, Product Code BTR)

E. Device Description

The ISIS Tube is a single-use, sterile tracheal tube made of polyvinyl chloride tube body, cuff inflation line and a compatible pilot balloon and one-way valve. A radiopaque line is incorporated into the full length of the tracheal tube. Each tracheal tube is supplied with an appropriately sized 15mm connector. ISIS Tube will be sold in Murphy eye style. Each tube has a dorsal lumen with an opening above the cuff and a male suction connector port attached to the tube which is close to the machine end of the tube. Access to the suction lumen is accomplished via a connection of the suction accessory pack (P/N 5-23000) directly to the male suction connector.

F. Indications for Use

The ISIS Tube is indicated for airway management by oral intubation during mechanical ventilation and anesthesia including the capability to aid in the removal of subglottic secretions.

G. Contraindications

There are no known contraindications.

H. Substantial Equivalence

The proposed ISIS Tube is substantially equivalent to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Sheridan HVT, Cuffed, Uncuffed Tracheal Tube	Teleflex Medical, Inc.	K822082	08/10/1982
Hi-Lo Evac and Evac II Endotracheal Tubes	Mallinckrodt Medical	K965132	03/20/1997
Portex Blue Line Sacett Suction Above the Cuff Tracheal Tube	Smiths Medical ASD, Inc.	K081086	08/13/2008

I. Summary of Testing

The proposed ISIS Tube device meets the following standards: ISO 5361, ISO 5356-1, ISO 10993, ISO 14971, and ISO 11135. Bench testing determined that the suction/aspiration capability of the ISIS Tube is equivalent to the predicate devices.

J. Substantial Equivalence

The proposed ISIS Tube is substantially equivalent in intended use, design, performance and principles of operation to the identified predicate devices cleared under 510(k)s K822082, K965132 and K081086. The differences between the ISIS Tube and the predicated devices are minor and raise no new issues of safety and efficacy. The ISIS Tube is substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. William Heard
Regulatory Affairs Specialist
Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, North Carolina 27709

OCT 29 2009

Re: K091761
Trade/Device Name: TELEFLEX ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: October 15, 2009
Received: October 16, 2009

Dear Mr. Heard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____

Device Name: TELEFLEX ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port

Indications for Use:

The TELEFLEX ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port is indicated for airway management by oral intubation during mechanical ventilation and anesthesia including the capability to aid in the removal of subglottic secretions.

Prescription Use XX
(Part 21 CFR 801 Subpart D)

Over-the-counter use __
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091761